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| 10/823,369 | 04/13/2004 | Marc Richelsoph | 2184.00091 | 4869 |

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EXAMINER

STOKES, CANDICE CAPRI

ART UNIT

PAPER NUMBER

3732

DATE MAILED: 08/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The portion of the claims that recites "each arm comprising a thinned section adapted to break" is considered to be new matter. It is unclear where this is shown in the drawings and also it is unclear where this was presented in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4,6,9-14,16-21,23,27-28 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Richelsoph (USPN 5,964,760). Richelsoph discloses a screw and rod fixation assembly comprising a screw 12" with a screw head 40 having fixing means comprising insert 70 and body 30"". The insert 70 includes an inner passageway for fixing the screw 12" from

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movement relative to the assembly. The fixing means can both automatically and compressively fix screw 12" from movement. As Richelsoph explains "once the screw head 40"" is fully inserted into the pocket, the insert 70 snaps onto the screw head 40"". In this condition, polyaxial movement can be achieved. Locking can be achieved in two manners. The body 30"" can be pulled up relative to the screw 12"" with an instrument (not shown) without the rod 20"" being in place or pulled by the nut 26"" as the nut 26"" is tightened over the rod 20"". This provides the surgeon with the option of adjusting the screw angle for abnormal anatomy and locking it prior to locking the rod 20"" to the assembly 10"" or locking the screw 12"" and the rod 20"" interfaces simultaneously when correction is not required" (col.8, lines 23-31). The insert 70 of the fixing means, which is a substantially annular ring including an edge portion extending about a center axis and having a frustoconical surface tapering outwardly toward the edge portion for engaging the screw head 40"" while allowing a portion of the screw 12" to pass therethrough as shown in Fig. 7, having an inner surface wall having a gripping portion and a non-gripping portion. Rod seating means 16"" is operatively engaged with the fixing means for seating a rod therein. Because Richelsoph discloses the body 30"" can be pulled by nut 26"" which is used to tighten over rod 20"" by bringing the arms of the rod seating means together, it is inherent that there is at least some flexibility in the rod seating means. This also reads on claim 6. Locking means 22 comprising nut 26"" is for securing and engaging the rod and rod seating means. This also anticipates Claims 23,27-28 and 31. As to Claims 2 and 3, rod receiving means 16"", it includes a body portion 30"" having two arms 24"",14""extending therefrom and being substantially parallel relative to each other. The two arms 24"",14"" and the body portion 30"" form a U-shaped inner surface defining the seat portion thereof. Regarding

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As to Claims 9-11 and 17-18, the fixing means 14” includes an inner surface wall 44 having a gripping portion. Further, “the rod seating member 14” is then disposed over the head portion 40 of the screw element 12” by insertion of the head portion 40 into the seat 44. This is a snapping operation but allows for angular adjustment of the tubular member 14””(col. 6, lines 30-33).

Regarding Claims 12-13 and 19, the substantially tubular body has spaced parallel arms as shown in Fig. 5. As to Claim 14, inner surface 44 has an aperture. With regard to Claim 16, “the fixing means 70 is sufficiently collapsible to be snapped into the internal portion 72 of the body element 34”. This is accomplished by compressing the fixing means 70 and releasing it inside the internal portion 72. The assembly itself can be made from any durable material, such as carbon composites, nitinol, stainless steel, composite materials, plastics, and plastic compositions” (col.7, lines 65-67 & col8, lines 1-5). As to Claims 20-21, Richelsoph discloses rod seating means 70 with a top portion as shown in Fig. 9 considered to be a body portion with a tapered flexible portion 80 extending therefrom.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5,7-8,15, and 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richelsoph in view of Schlapfer et al (USPN 5,520,689). Richelsoph discloses the claimed invention except for the locking means being a set screw with a threaded outer surface.

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Schlapfer et al teaches a set screw 7 with a threaded outer surface 12, which engages the threaded inner surface 11. As to Claims 8 and 25, Richelsoph discloses “in this manner as the locking mechanism 22 forces the inner wall 18 to contour around and engage the rod 20 seated therein” (col. 3, lines 46-49). The embodiment as shown in Fig. 8 of Richelsoph functions in the same manner. The Schlapfer et al patent shows that the same function will be performed if the threads of the rod seating means disclosed by Richelsoph were on the inner portion of the arms and a locking screw with threads on its outer portion were used to engage the rod into the seating means. It would have been obvious to one having ordinary skill in the art to incorporate the threaded outer and inner surfaces as taught by Schlapfer et al into the screw and rod fixation assembly disclosed by Richelsoph, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art (*In re Einstein*, 8 USPQ 167), and further in order to provide a more secure engagement between the locking member and the rod seating means.

Allowable Subject Matter

Claim 26 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed 04/04/06 have been fully considered but they are not persuasive. Based on the arguments presented, the Examiner is restating the position as the amendments and remarks are still directed toward the previous arguments.

The Examiner submits the Richelsoph '760 patent discloses "this embodiment being characterized by including a screw head receiving insert generally shown at 70 which is moveable within the assembly 10"" between a locked position as shown in FIGS. 7 and 8 entrapping the screw head 40"" therein and an unlocked position wherein the screw head 40"" enters or escapes, as shown in FIGS. 5 and 6. That is, this embodiment of the invention includes a single unit capable of receiving a screw head 40"" therein and then allowing for polyaxial adjustment of the screw head relative to the assembly and then locking of the screw head within the assembly without requirement of additional elements to the assembly" (col. 7, lines 13-25). Furthermore, the present invention discloses "as described above, the fixing mechanism 18, and more particularly the gripping portion 22, securely grips the screw head 14 through compression forces generated by the spring action of the semi-flexible material. To reiterate, the spring reaction occurs from the screw head 14 stretching the gripping portion 22 beyond its original dimensions, but within the material's elastic range" ([0054]). Similar compression forces are applied in both instances thus, the present invention is anticipated by Richelsoph in the '760 patent. Accordingly, claims 1-21,23-25,27-28, and 31 remain rejected.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Candice C. Stokes whose telephone number is (571) 272-4714. The examiner can normally be reached on 8:00am - 4:30pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cris Rodriguez can be reached on (571) 272-4964. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Candice C. Stokes



CRIS L. RODRIGUEZ
PRIMARY EXAMINER